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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,795	08/19/2003	Frederic J. DeSavage	P5026R1	6007

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GENENTECH, INC.

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SOUTH SAN FRANCISCO, CA 94080

EXAMINER

YAO, LEI

ART UNIT PAPER NUMBER

1642

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/643,795	Applicant(s) DESAUVAGE ET AL.	
	Examiner Lei Yao, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-18 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/20/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>exhibit A and B</u> . |

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I (claim 17 and linking claim, claim 16) in the reply filed on 7/17/06 is acknowledged.

Claims 16-18 are pending. Claim 18 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 16-17 are examined on the merits.

Information Disclosure Statement

The information disclosure statement (s) (IDS) submitted on 9/20/04 are/is considered by the examiner and initialed copies/copy of the PTO-1449 are/is enclosed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The claims are drawn to a method of diagnosing the presence of prostate tumor in a mammal comprising determining the levels of expression of a gene encoding the polypeptide shown as SEQ ID NO: 123 in the test sample, wherein the higher levels of expression of the gene is indicative of the

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presence of a prostate tumor in the mammal and wherein the level of expression of the gene is detected by in situ hybridization or RT-PCR.

1. Claims 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Xu et al., (US Patent, 6262245, Date of Patent, 7/17/01) as evidenced by sequence search (exhibit A).

Xu et al., disclose a method of diagnosing a prostate tumor by determining the levels of prostate tumor related gene expressions in a prostate tumor tissue by RT-PCR comprising the expression of a nucleic acid encoding a polypeptide, which is 100% identical to the amino acid residues at 766-1085 of SEQ ID NO: 123 (see sequence search exhibit A; column 14 and 17, line 37-42, SEQ ID NO: 109, cDNA clone J1-17). Xu et al., disclose that, for PCR, the oligonucleotide primers/probe having at least 15 contiguous nucleotide of DNA selectively from the gene (SEQ ID NO:109) is employed in a prostate tumor sample and hybridized to cDNA derived from the samples (col 14-15). Xu et al., also disclose an example of determining the levels of mRNA expression in the prostate tumor tissues compared to normal prostate tissues by RT-PCR and a result indicating that the gene expression (J1-17) is significantly elevated in the prostate tissues (col 19, example 2).

Since claimed method is not drawn to a specific oligonucleotide as primers or a probe for RT-PCR for determining the expression of a gene encoding a protein shown as SEQ ID NO: 123 and since the method disclosed by Xu et al., using the same method steps and the primers having any 15 oligonucleotide from the same sequences as claimed, method disclosed by Xu et al., anticipates the claimed method of diagnosing the presence of a prostate tumor by determining the levels of expression of a gene encoding a polypeptide shown as SEQ ID NO: 123 by RT-PCR.

2. Claims 16-17 are rejected under 35 U.S.C. 102(a) and 102 (e) as being anticipated by Gish et al., (WO 02/30268, published date 4/18/02, and effective filing date, 10/13/ 2000) as evidenced by sequence search (exhibit B).

Gish et al., disclose a method of diagnosing a prostate cancer by detecting a prostate cancer-associated transcript (mRNA) in a cell from a patient comprising determining a nucleic acid encoding a polypeptide, which is 99.6% identical to the amino acid sequence of SEQ ID NO: 123, different at first 4

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amino acids (see sequence search, exhibit B; page 322-323 and 139, protein sequence, SEQ ID NO: 53 having accession no: AA431407; page 339-340, corresponding DNA sequence, SEQ ID NO:105). Gish et al., disclose the method comprising contacting a biological sample from a prostate patient with a polynucleotide probe that selectively hybridizes to the sequence (page 3). Gish et al., further disclose that the nucleic acid comprising mRNA expressed in prostate cancer sample is detected by *in situ* hybridization or PCR (page 59, 61, and 91-97, example 1). Gish et al., also disclose that expressing the specific prostate cancer gene in the prostate tumor tissue (accession no: AA431407) is up-regulated compared to the normal prostate tissue (Table 4, page 139, line 3).

Since claimed method is not drawn to a specific oligonucleotide as primers or a probe for the *in situ* hybridization or RT-PCR, the method disclosed by Gish et al., anticipates the claimed method of diagnosing the presence of a prostate tumor comprising determining the levels of expression of a gene encoding the polypeptide shown as SEQ IDNO: 123 by an *in situ* hybridization or RT-PCR.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LY

Lei Yao, Ph.D.
Examiner
Art Unit 1642


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER